

## **REMARKS/ARGUMENTS**

### **Claim Amendments**

By the present amendment, claim 12 has been amended to delete "at risk of metastasis" and insert "or whether the patient having said cancer has a poor outcome" and to clarify that the sample is from non-metastatic cancer. Support for the amendments can be found on page 14 and on page 43, lines 5-21. In addition, non-elected claims 1-9, 11, 13-33 and 40-45 have been cancelled. The amendments to the claims have been made without prejudice and without acquiescing to any of the Examiner's objections. Applicant reserves the right to pursue any of the deleted subject matter in a further divisional, continuation or continuation-in-part application. No new matter has been entered by the present amendment and its entry is respectfully requested.

The office action dated July 17, 2009 has been carefully considered. It is believed that the amended claims and the following comments represent a complete response to the Examiner's rejections and place the present application in condition for allowance. Reconsideration is respectfully requested.

### **35 U.S.C. 102**

The Examiner rejected claims 10, 12, 34-38 and 39 under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US Patent No. 6,613,515, issued Sept. 2, 2003, filed Aug. 15, 2000). We note that in the previous office action the Examiner made the rejection under 35 U.S.C. 102(e).

According to the Examiner, Xu et al. discloses that podocalyxin is overexpressed in ovarian carcinoma tissues (Table VI) compared to normal ovarian tissue and that the mRNA and protein may be detected. The Examiner noted the arguments provided in the response dated April 21, 2009 but maintained the rejection because the feature that the Applicant relied on in the previous response is not recited in the rejected claim(s). According to the Examiner, the active steps for detecting cancer in the elected claims, including metastatic cancer, comprising measuring expression levels of podocalyxin are disclosed in Xu et al.

Applicant respectfully disagrees with the Examiner's rejection of claim 10. Claim 10 is directed to monitoring progression of cancer and this claim requires the additional active step of repeating the detection at a later timepoint for the same patient and comparing the levels from the first timepoint and second timepoint, steps that are not disclosed in Xu et al. The term "control sample" is defined in the specification at page 14 as "any sample that can be used to establish a base or normal level...". A base level when determining whether a cancer is metastatic or whether a patient having said cancer has a poor outcome includes levels where a cancer is not metastatic. With respect to claim

12 and claims dependent thereon, claim 12 has been amended to clarify the "control sample". In particular, claim 12 has been amended to recite "a control sample from non-metastatic cancer" and thus contains a second active step of comparing the podocalyxin expression levels of the sample with a non-metastatic cancer sample. As stated in the previous response, Xu et al. merely discloses that podocalyxin expression is increased in cancer compared to non-cancer. Thus, Applicant respectfully submits that Xu et al. does not anticipate the present claims.

The Examiner rejected claims 10, 12 and 35-38 under 35 U.S.C. 102(b) as being anticipated by Erlander et al. (US Patent Application No: 2004/0002067, published Jan 1, 2004, filed December 21, 2001). We note that in the previous office action the Examiner made the rejection under 35 U.S.C. 102(e).

According to the Examiner, Erlander et al. discloses that podocalyxin is upregulated in ductal carcinoma and invasive ductal breast carcinoma compared to patients with normal and hyperplastic breast tissue. The Examiner noted the arguments provided in the response dated April 21, 2009 but maintained the rejection because the feature that the Applicant relied on in the previous response is not recited in the rejected claim(s). According to the Examiner, the active steps for detecting cancer in the elected claims, including metastatic cancer, comprising measuring expression levels of podocalyxin are disclosed in Erlander et al.

As stated above, Applicant respectfully disagrees with the Examiner's rejection of claim 10. Claim 10 is directed to monitoring progression of cancer and this claim requires the additional active step of repeating the detection at a later timepoint for the same patient and comparing the levels from the first timepoint and second timepoint, steps that are not disclosed in Erlander et al. With respect to claim 12 and claims dependent thereon, claim 12 has been amended to clarify the "control sample". In particular, claim 12 has been amended to recite "a control sample from non-metastatic cancer" and thus contains a second active step of comparing the podocalyxin expression levels of the sample with a non-metastatic cancer sample. As stated in the previous response, Erlander et al. merely discloses that podocalyxin expression is increased in cancer compared to normal/atypical hyperplasia (non-cancer). Thus, Applicant respectfully submits that Erlander et al. does not anticipate the present claims.

In view of the above, Applicant respectfully requests that the rejection to the claims under 35 U.S.C. 102(b) and/or 102(e) be withdrawn.

### **35 U.S.C. 112**

The Examiner rejected claims 12 and 34-38 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting metastatic cancer, does not reasonably provide enablement for a method for determining the risk of metastasis. In response, claim 12 (and thus dependent claims 34-38) have been amended to delete "risk of metastasis". Claim 12 has been amended to recite "or whether the patient having said cancer has a poor outcome". Applicant respectfully

submits that the specification is enabling for determining whether a patient having cancer has a poor outcome based on the comparison of expression level of podocalyxin with other cancer associated markers as shown in Example I of the specification, and in particular, at page 43, lines 5-21 and Tables 2 and 3.

The Examiner rejected claims 12 and 34-38 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicant has replaced "risk of metastasis" with "whether the patient having said cancer has a poor outcome" which finds written support at page 43, lines 5-21 of the specification.

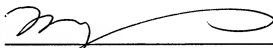
In view of the above, Applicant respectfully requests that the rejections under 35 U.S.C. 112, first paragraph, be withdrawn.

The Commissioner is hereby authorized to charge any fee (including any claim fee) which may be required to our Deposit Account No. 02-2095.

In view of the foregoing comments and amendments, we respectfully submit that the application is in order for allowance and early indication of that effect is respectfully requested. Should the Examiner deem it beneficial to discuss the application in greater detail, he is kindly requested to contact the undersigned by telephone at (416) 957-1678 at his convenience.

Respectfully submitted,

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